

Date: Aug. 27, 2013

K131068

510(k) Summary

3-1. 510(k) owner (submitter)

1) Name	Kuraray Noritake Dental Inc.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in US	Goro Asanuma KURARAY AMERICA, INC. 33 Maiden Lane, 6th Floor, New York, NY 10038 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	TEETHMATE DESENSITIZER
2) Classification name	Calcium hydroxide cavity liner (21 CFR section 872.3250. Product code: EJK)
3) Common name	Tooth Desensitizer

AUG 27 2013

3-3. Predicate Device

1) TEETHMATE DESENSITIZER	510(k) Number: K122421
	Classification: Calcium hydroxide cavity liner
	Product Code: EJK
	21 CFR Section: 872.3250
	Applicant: Kuraray Noritake Dental Inc.

3-4. Device Description

The subject device consists of POWDER which contains Calcium Phosphate as a major component and LIQUID which mainly contains water. POWDER and LIQUID are mixed to obtain paste. The paste applied to the affected area transforms to a hardened material of hydroxyapatite and it suppresses hypersensitivity by sealing the dentin tubules and microcracks in the enamel.

This is an application for a partial change of the predicate device. The information of the predicate device is put on the following website.

http://www.accessdata.fda.gov/cdrh_docs/pdf12/K122421.pdf.

In this application, we want to change the wording of one of the "Indications for use". In the former application dossier, the indication [3] was described as: "Treatment of tooth surface after bleaching". In this application we will change the wording of the indication [3] as follows: "Treatment of tooth surface before and/or after bleaching" in order to improve the usability for dentists based on the fact that the subject device works by physically sealing the dentinal tubules and/ or microcracks in the enamel whether before or after bleaching teeth. Accordingly, this amendment does not substantially affect the effectiveness and performance of the medical device. And the efficacy and safety of the subject device are substantially equivalent to those of the device whose "indication for use" is unchanged.

3-5. Statement of Intended Use

TEETHMATE DESENSITIZER is indicated for reduction of tooth hypersensitivity by the following treatments:

- [1] Treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion
- [2] Treatment of dentin after mechanical tooth cleaning, scaling and/or root planing
- [3] Treatment of tooth surface before and/ or after bleaching
- [4] Treatment of prepared dentin for fillings and/or prosthetic restorations

3-6. Substantially Equivalence Discussion

1) Intended uses

Predicate device	Subject device
<p>TEETHMATE DESENSITIZER is indicated for reduction of tooth hypersensitivity by the following treatments:</p> <ul style="list-style-type: none">[1] Treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion[2] Treatment of dentin after mechanical tooth cleaning, scaling and/or root planing[3] Treatment of tooth surface after bleaching[4] Treatment of prepared dentin for fillings and/or prosthetic restorations	<p>TEETHMATE DESENSITIZER is indicated for reduction of tooth hypersensitivity by the following treatments:</p> <ul style="list-style-type: none">[1] Treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion[2] Treatment of dentin after mechanical tooth cleaning, scaling and/or root planing[3] Treatment of tooth surface before and/ or after bleaching[4] Treatment of prepared dentin for fillings and/or prosthetic restorations

2) Chemical ingredients / Safety

The chemical composition of subject device is the same as that of the predicate device. Therefore, the subject device is equivalent to the predicate device in terms of the safety.

3) Technological characteristics/ Effectiveness and Performance

The subject device contains the same chemical ingredients and uses the same hypersensitivity-suppressing mechanism as the predicate device, and hence it can be said that their technological characteristics/ effectiveness and performance are the same.

And it was confirmed that there was no difference in sealing performance between before and after bleaching teeth when investigated the ability of the subject device to seal microcracks in the enamel before and after bleaching. Moreover, it was confirmed that the subject device used before bleaching did not affect the bleaching performance when investigated the effect of the subject device on the performance of the bleaching material.

3-7. Biocompatibility

The subject device is categorized the external communicating device (tissue/ bone/ dentin) and of permanent contact device.

All chemical ingredients of the subject device are the same as those of the predicate device. We have already shown the biocompatibility of the predicate device in its application.

Conclusion

The test results exhibited that the subject device was substantially equivalent in effectiveness and biocompatibility to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 27, 2013

Kuraray Noritake Dental, Incorporated
Mr. Michio Takigawa
Quality Assurance Department
OTE Center Building 7F
1-1-3, Otemachi
Chiyoda-KU, Tokyo 100-0004
JAPAN

Re: K131068
Trade/Device Name: TEETHMATE DESENSITIZER
Regulation Number: 21 CFR 872.3250
Regulation Name: Calcium Hydroxide Cavity Liner
Regulatory Class: II
Product Code: EJK
Dated: August 2, 2013
Received: August 5, 2013

Dear Mr. Takigawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131068

Device Name: TEETHMATE DESENSITIZER

Indications for Use:

TEETHMATE DESENSITIZER is indicated for reduction of tooth hypersensitivity by the following treatments:

- [1] Treatment of dentin exposed by toothbrush abrasion, gingival recession, periodontal disease and/or acid erosion
- [2] Treatment of dentin after mechanical tooth cleaning, scaling and/or root planing
- [3] Treatment of tooth surface before and/ or after bleaching
- [4] Treatment of prepared dentin for fillings and/or prosthetic restorations

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use N/A
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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